

## Exhibit 76

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# Patient advocacy group funded by success of painkiller drugs, probe finds

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The news about narcotic painkillers is increasingly dire: Overdoses now kill nearly 15,000 people a year — more than heroin and cocaine combined. In some states, the painkiller death toll exceeds that of car crashes.

The head of the Centers for Disease Control and Prevention has declared the overdoses from opioid drugs like OxyContin an “epidemic.” And a growing group of experts doubts that they work for long-term pain.

But the pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation’s largest advocacy group for pain patients. Its message: The risk of addiction is overblown, and the drugs are underused.

What the nonprofit organization doesn’t highlight is the money behind that message.

The foundation collected [nearly 90 percent](#) of its \$5 million in funding last year from the drug and medical-device industry — and closely mirrors its positions, an examination by ProPublica found.

Although the foundation maintains it is sticking up for the needs of millions of suffering patients, records and interviews show that it favors those who want to preserve access to the drugs over those who worry about their risks.

Some of the foundation’s [board members](#) have extensive financial ties to drugmakers, ProPublica found, and the group has lobbied against federal and state proposals to limit opioid use. [Painkiller sales have increased fourfold](#) since 1999, but the foundation argues that pain remains widely undertreated.

The group says industry money has had no effect on its advocacy.

“I’m convinced with every shred of my body that our interest is improving the lives of people affected by pain,” said Will Rowe, the foundation’s chief executive, “and we want to do that the best way we can.”

The problem isn’t opioids, Rowe and other group leaders say. It’s poorly trained doctors who prescribe them too easily or in excess.

Yet, critics say the Baltimore-based foundation is making it harder to address a major public-health problem.

“If you were a drug company, wouldn’t it be smart to make it look like you had a patient-oriented group?” said Gary Franklin, a Washington state official who tussled with the foundation over new restrictions on high-dose painkillers.

Its funding makes the group “one and the same” with the pain industry, Franklin said.

ProPublica's review found that the foundation's guides for patients, journalists and policymakers play down the risks associated with opioids and exaggerate their benefits. Opioids, derived from the poppy plant, reduce the perception of pain by attaching to opioid receptors in the brain, spinal cord and elsewhere in the body.

Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research.

The group's board includes some patients but also doctors who are paid to speak and consult for drug companies, a researcher whose clinic has relied on their funding for survival and a public-relations executive whose firm represents them.

Last year, one board member was the [lead author of a study](#) about a Cephalon drug. Cephalon sponsored the study, and its employees were co-authors. The study found that the drug, Fentora, was "generally safe and well-tolerated" in non-cancer patients even though it is only approved for severe cancer pain.

Andrew Kolodny, a New York psychiatrist who heads Physicians for Responsible Opioid Prescribing, said the foundation has built credibility with politicians and regulators who might not be aware of the extensive industry ties.

"I don't think they realize that in many ways the American Pain Foundation is a front for opioid manufacturers," Kolodny said.

Rowe, however, said that with scant options to treat chronic pain, opioids have made the difference between days and nights of agony and a return to productive life for millions of patients. Critics, he said, have a hard time understanding that these patients are willing to risk serious side effects to gain relief.

"Policymakers can go to bed at night and say, 'Well, I protected society' " by restricting access to a risky painkiller, Rowe said. "The person with pain or the person with cancer could say: 'You know, I'm sorry. I'm living with this, and I want to take this chance.' "

### **Sales skyrocketed**

In the late 1980s and early '90s, physicians who cared for pain patients excitedly embraced opioids as a low-risk treatment for suffering.

Many doctors, especially those providing primary care, had long ignored pain as a condition that warranted its own treatment.

But in recent years, pain doctors split. Some began decrying the increasingly widespread use of opioids and questioned whether the drugs worked. Others, like the foundation's leaders, said the drugs were being unfairly maligned, making pain patients feel like criminals and discouraging doctors from prescribing them.

Despite the debate, sales of the drugs have skyrocketed.

Last year, \$8.5 billion worth of narcotic painkillers were sold in the United States, according to the prescription-tracking company IMS Health. Enough of the drugs were prescribed last year to “medicate every American adult around the clock for a month,” the CDC said.

Some of the pills have become household names: Vicodin, Percocet, OxyContin. On its own, OxyContin, an extended-release painkiller, accounted for \$3.1 billion in sales last year, up from \$752 million in 2006, according to IMS Health.

“Right now, the system is awash in opioids, dangerous drugs that got people hooked and keep them hooked,” CDC Director Thomas Frieden said in a recent news briefing.

Today, the American Pain Foundation’s Web site offers publications for patients, policymakers and even journalists. Each depicts the benefits of opioids, and each is underwritten by the makers of those drugs.

Its patient guide, paid for by four companies, discusses several treatments for pain. It says such pain relievers as aspirin, ibuprofen and naproxen commonly cause gastrointestinal bleeding or ulcers, delay blood clotting, decrease kidney function and could increase the risk of stroke or heart attack. And it warns patients to use these pain pills at the lowest dose and stop them unless clearly needed.

The side effects of opioids, on the other hand, are minor, and most go away “after a few days,” the foundation’s guide says. Patients, it says, shouldn’t worry if they need more of a drug. They are not developing an addiction.

“Many times when a person needs a larger dose of a drug,” the guide says, “it’s because their pain is worse or the problem causing their pain has changed.”

Another guide, written for journalists and supported by Alpharma Pharmaceuticals, likewise is reassuring. It notes in at least five places that the risk of opioid addiction is low, and it references a 1996 article in Scientific American, saying fewer than 1 percent of children treated with opioids become addicted.

But the cited article does not include this statistic or deal with addiction in children. “I would much prefer that they would put in there something that could be substantiated by a real reference,” said Leonard Paulozzi, a CDC medical epidemiologist specializing in drug overdoses.

A recent report by the National Institute on Drug Abuse said estimates of addiction among chronic pain patients using opioids range from 3 percent to as high as 40 percent.

Rowe, the foundation’s chief executive, acknowledged that some of its publications need updating. He pointed to additional materials on the group’s new PainSAFE Web site, which includes a broader description of the risks. But the foundation continues to post outdated guides and even refers to them in newer materials.

#### **Arguing in court**

The foundation doesn’t just offer advice about opioids; it takes its arguments into court.

In 2005, it filed a friend-of-the-court brief in the U.S. Court of Appeals for the 4th Circuit in support of William Hurwitz, a pain doctor in Virginia who had been convicted on 50 counts of drug trafficking.

The doctor had been accused of prescribing a single patient as many as 1,600 Roxicodone pain pills in one day. Hurwitz allegedly had prescribed that patient alone more than 500,000 pills between July 1999 and October 2002.

The pain foundation and its allies argued that the jury instructions in the case didn't distinguish between criminal behavior and mistakes by a well-intentioned physician. "It is not drug dealing to prescribe opioids to patients that might be 'suspected' addicts or substance abusers," the foundation and two other groups wrote in a brief.

Rowe said the foundation intervened in the case on principle, fearing the drugs would be "demonized." The appeals court threw out the conviction, but [Hurwitz was retried and convicted on 16 counts of trafficking](#).

Years earlier, the foundation opposed several pain patients who had sued Purdue Pharma in an Ohio county court for obscuring the risks of OxyContin.

The foundation filed a friend-of-the-court brief backing Purdue, arguing that the health of all pain patients would be harmed if the class-action lawsuit went forward because doctors would be fearful of prescribing opioids.

Ohio was plagued by "opiophobia" according to a brief written by the foundation and two smaller pain nonprofits.

The Ohio Supreme Court decided in 2004 not to allow a class action.

In a separate federal case in 2007, Purdue pleaded guilty to misbranding OxyContin "in an effort to mislead and defraud physicians and consumers" and agreed to pay \$600 million in penalties, according to a statement from prosecutors. Three top officials also pleaded guilty to misdemeanors and agreed to pay \$34.5 million.

Two months after the conviction, however, then-foundation Chairman James Campbell praised Purdue in a statement to a U.S. Senate committee.

"I believe Purdue and its management deserve recognition for their contribution to the welfare of these many patients," Campbell wrote. Prosecuting the executives, he wrote, sent a "chilling message to those who dare to develop high-risk drugs for important diseases."

The foundation routinely weighs in on state and federal debates over how to regulate painkillers. But although its officials blame poorly educated physicians for the growing problems with opioids, it fought against a 2009 suggestion by the Food and Drug Administration that doctors be certified to ensure they understood the drugs' risks.

The FDA backed off. Such education remains voluntary.

#### Questions about benefits

Missing from the American Pain Foundation literature is any suggestion that the drugs don't work for many chronic pain sufferers.

Recent editorials in medical journals and scientific reviews cite little evidence of long-term benefit.

Most of the clinical trials for opioids to treat chronic pain "were small, lasted less than 16 weeks and excluded patients with a history of substance abuse, psychiatric illness and depression, who are at increased risk for opioid misuse and abuse," three physicians wrote in an editorial this year in the Archives of Internal Medicine.

"How can a therapy be considered if there's no evidence that it works and there's evidence of lots of side effects?" Mitchell Katz, one of the authors and director of the Los Angeles County Department of Health Services, said in an interview.

Rowe said he knows plenty of patients for whom the drugs work, "and their lives are together because they use them."

The foundation board's chairman and president, Scott Fishman, is stepping down at the end of the month. In a statement to ProPublica, he said that his views have evolved and that he now believes opioids are overused and addictive. But he defended the group.

"I have not always agreed with APF positions and have had disagreements with some APF leaders and patient advocates about many issues in pain management, including the appropriate place of chronic opioid therapy," wrote Fishman, chief of pain medicine at the University of California at Davis.

"Nonetheless, I have always believed that patients in pain in the United States need strong patient advocacy, which APF has offered."

*Weber and Ornstein report for ProPublica, a nonprofit investigative newsroom in New York City. A longer version of this article is available at [www.propublica.org](http://www.propublica.org).*

 31 Comments

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